SECTION 5 - 510(K) SUMMARY

DEC 13 2010

Date of Summary: November 26, 2010

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Official Contact: Cheryl Brown – QA / RA Manager

Proprietary Name: MED-RX Pediatric Feeding Tube and Accessories
Common Name: Feeding Tube or NG/OG Tube
Classification Name: Gastrointestinal tube and accessories
Class: Class II
Product Code: FPD
Predicate Devices: Vygon Nutrisafe 2 (K060944)
NeoChild SafeChild Infant Feeding Tube and Accessories (K082710)

Device Description

The MED-RX Pediatric Feeding Tube is intended to be used for nasogastric/oralgastric enteral feeding as directed by a physician. Accessories to be offered alongside the MED-RX Pediatric Feeding Tubes include MED-RX Enteral Extension Sets of various configurations. The MED-RX Enteral Extension Set is intended to be used to deliver fluids from the nutritional source to an existing non-luer pediatric feeding tube. The MED-RX Pediatric Feeding Tubes and Enteral Extension Sets feature non-luer enteral only connectors to decrease the risk of accidental misconnection. All devices are sterile, single-use, and latex free. The MED-RX Pediatric Feeding Tube and Accessories are for pediatric use only. Accessories may be sold with MED-RX Pediatric Feeding Tubes or separately.

Indications for Use

The **MED-RX Pediatric Feeding Tube and Accessories** are disposable, single use enteral feeding devices featuring non-luer enteral only connectors. The **MED-RX Pediatric Feeding Tube** is intended to be used for nasogastric/oralgastric enteral feeding, as directed by a physician. The **MED-RX Enteral Extension Set** is an accessory to the MED-RX Pediatric Feeding Tube, to be used to deliver fluids from the nutritional source to an existing non-luer pediatric feeding tube. The **MED-RX Pediatric Feeding Tube and Accessories** are for hospital use, pediatric patient use only, and are not intended for use beyond 30 days.

Substantial Equivalence:

The information provided in the premarket notification demonstrates that the proposed device is substantially equivalent to legally marketed devices. The proposed MED-RX Pediatric Feeding Tube and Accessories is substantially equivalent to the Vygon Nutrisafe 2 (K060944) and the NeoChild SafeChild Infant Feeding Tubes and Accessories (K082710). Both the proposed and the predicate devices have the same intended use for nasogastric/oralgastric enteral feeding as directed by a physician. A comparison of features and principles of operation between the proposed device and predicate devices is provided in Table 1.

Table 1: Comparison between MED-RX Pediatric Feeding Tube, Vygon Nutrisafe 2 (K060944), and NeoChild SafeChild Infant Feeding Tube and Accessories (K082710)

Attribute	Proposed Device: MED-RX Pediatric Feeding Tube and Accessories	Predicate Device: Vygon Nutrisafe 2 (K060944)	Predicate Device: NeoChild SafeChild (K082710)
Indications for Use	For nasogastric/oralgastric enteral feeding as directed by a physician	Same	Same
Intended Population	Pediatrics	Same	Same
Intended Environment of Use	Hospital	Same	Hospital, home, or environments where feeding tube is required
System Configuration	Tube with integral radiopaque line, depth markings, and non-luer enteral only connector	Same	Same
Materials	PVC, polyurethane, various medical grade plastics	Same	Same
Connector	Non-luer enteral only slip fit connector	Non-luer enteral only threaded connector	Non-IV enteral connector
Packaging	Pouch, sealed	Same	Same
Sterility	EO	EO	EO
Single Use	Yes	Yes	Yes

Summary of Differences

There are no significant differences between the proposed MED-RX Pediatric Feeding Tube and Accessories and the predicate devices, Vygon Nutrisafe 2 (K060944) and NeoChild SafeChild Infant Feeding Tube and Accessories (K082710). Similarities between the proposed device and the predicate devices include identical indications for use and intended populations. Both the proposed device and the predicate device feature non-luer enteral only connectors and are manufactured from equivalent materials. The MED-RX Pediatric Feeding Tube and Accessories, the Vygon Nutrisafe 2, and the NeoChild SafeChild Infant Feeding Tube and Accessories are single-use, sterile devices, packaged in peelable paper/poly pouches. All devices are sterilized using ethylene oxide. Any minor differences between the proposed device and the predicate

have been evaluated to have no impact on safety or effectiveness of the MED-RX Pediatric Feeding Tube and Accessories, and therefore the devices can be considered equivalent.

Non-Clinical Test Summary

Verification of functional performance of the MED-RX Pediatric Feeding Tubes and Accessories has been performed and successfully completed. The MED-RX Pediatric Feeding Tubes and MED-RX Enteral Extension Sets were subject to numerous performance tests including tensile strength of the bonded joints and of the tubes, and resistance to liquid leakage under pressure and under vacuum. The MED-RX Pediatric Feeding Tube and Accessories were also tested for connector separation, device compatibility with other non-luer medical devices, and for determination of flow rate. The MED-RX Pediatric Feeding Tubes and MED-RX Enteral Extension Sets have successfully completed all required performance testing, as summarized in Table 2.

Table 2: Summary of Performance Test Results

Test	Pass/Fail Criteria	Result
Feeding Tube Tensile Strength Test	Withstand tensile force of: 2 lbf (OD ≤ 2 mm) 4 lbf (OD > 2 mm)	PASS PASS
Extension Set Tensile Strength Test	Withstand tensile force of 4 lbf	PASS
Leakage under Pressure	No leakage or separation under 50 kPa	PASS
Leakage under Vacuum	No leakage or separation under vacuum	PASS
Connector Separation	Withstand tensile force of 3.37 lbf (15 N)	PASS
Device Compatibility	Incompatible with other recognized non-luer medical devices	PASS

Latex Content

The MED-RX Transfer Sets were tested for natural rubber latex content using a Modified Lowry Method. The devices were found to contain less than 0.04% latex and are therefore considered to not contain natural rubber latex. The testing was completed by Wuxi AppTec.

Summary of Sterilization

Each of the MED-RX Pediatric Feeding Tubes and Accessories is individually packaged using a medical grade peelable synthetic polymer reinforced paper with a film backing, and sterilized using ethylene oxide. Please see Table 3 for a summary.

Table 3: Sterilization Summary

Test Description	Standard	Results
Method of Validation	ANSI/AMMI/ISO 11135:1994	Validated to a Sterility Assurance Level of 1×10^{-6}
EO Sterilization Residuals	ISO 10993-7: 2008	Pass
Bacterial Endotoxins	ANSI/AAMI ST72:2002	Pass

Summary of Biocompatibility Tests

Biocompatibility testing was successfully completed on sterile finished devices. The MED-RX Pediatric Feeding Tubes and Accessories are classified as surface contacting devices with prolonged mucosal membrane contact. A summary of the testing completed and the relevant standards are listed in Table 4.

Table 4: Biocompatibility Test Summary

Test Description	Standard	Results
ISO MEM Elution with L-929 Mouse Fibroblast Cells (Cytotoxicity)	ISO 10993-5: 2009	Product code 54-3680RU, 54-8242ORU, and 54-7069U are considered non-toxic.
Intracutaneous Reactivity Test	ISO 10993-10: 2010	Product code 54-3680RU, 54-8242ORU, and 54-7069U are considered a non-irritant.
Guinea Pig Maximization Sensitization Test (Method of Biomaterial Extracts)	ISO 10993-10:2002	Product code 54-3680RU, 54-8242ORU, and 54-7069U did not elicit a sensitization response.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Cheryl Brown
QA/RA Manager
Benlan, Inc.
2760 Brighton Road
OAKVILLE ONTARIO
CANADA L6H 5T4

DEC 13 2010

Re: K100700
Trade/Device Name: MED-RX Pediatric Feeding Tube and Accessories
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: FDP
Dated: December 10, 2010
Received: December 10, 2010

Dear Ms. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

DEC 13 2010

510(K) Number (If Known): K100700

Device Name: MED-RX Pediatric Feeding Tube and Accessories

Indications For Use:

The **MED-RX Pediatric Feeding Tube and Accessories** are disposable, single use enteral feeding devices featuring non-luer enteral only connectors. **The MED-RX Pediatric Feeding Tube** is intended to be used for nasogastric/oralgastric enteral feeding, as directed by a physician. The **MED-RX Enteral Extension Set** is an accessory to the MED-RX Pediatric Feeding Tube, to be used to deliver fluids from the nutritional source to an existing non-luer pediatric feeding tube. The **MED-RX Pediatric Feeding Tube and Accessories** are for hospital use, pediatric patient use only, and are not intended for use beyond 30 days.

Prescription Use:	✓	AND/OR	Over-the-Counter Use	N/A
(Part 21 CFR 801 Subpart D)			(21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K100700